REMARKS

Claims 25, 27 and 30-33 are pending. Claim 25 has been amended. Claims 26, 28 and 29 have been cancelled.

Claim Rejections under 35 U.S.C. § 102(e)

Claims 25-29, 31 and 32 have been rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,719,998 to Golomb et al. Golomb discloses pharmaceutical-containing nanoparticle compositions for the prevention or treatment of restenosis. Golomb further discloses coating these compositions onto a stent. It is the position of the Examiner that Golomb teaches the invention as presently claimed. This is not the case.

Claim 25 recites "...adding polymeric particles containing a therapeutic substance to a fluid form of a[n]...coating material wherein the coating material includes a polymeric material dissolved in a solvent; applying the fluid form of the coating material... to an implantable medical device; and solidifying the coating material... by allowing the solvent to evaporate..."

Nowhere does Golomb disclose, either expressly or inherently, a coating material that includes a polymeric material dissolved in a solvent nor does Golomb disclose applying a fluid form of the coating material to a medical device and solidifying the coating material by allowing the solvent to evaporate.

Golomb, rather, simply mentions the use of "...liquid carriers known in the art..." (Col. 6, lines 25-27) and lists a few examples. There is no mention of a polymeric material dissolved in a solvent as part of a coating material in addition to polymer particles. The liquid carriers of Golomb, e.g., agent-containing liposomes, are the coating material and no additional polymeric materials are present in the coating formulation. Furthermore, Golomb only discloses generally "...coating of the delivery system on a balloon or a stent..." (Col. 6, lines 51-54). In sum, there is no mention of polymeric particles added to a polymer solution so as to form a polymeric coating containing polymeric particles.

Because Golomb does not disclose, either expressly or inherently, the claim limitations of claim 25, the rejection of claim 25, and claims 27 and 30-33 dependent thereon, should be withdrawn.

Additionally, claim 31 is independently patentable. Nowhere does Golomb disclose, either expressly or inherently, that the polymeric particles have a hydrogel consistency. Golomb does not disclose any of the polymeric materials used in the methods of the present invention rather simply discloses that the nanoparticles, preferably liposomes, can be prepared by methods known in the art. Thus, the materials and methods of Golomb would not necessarily result in a hydrogel consistency as required by claim 31 of the application. Indeed, as disclosed in the present application, a hydrogel consistency depends on both materials and the manner of processing, e.g., dipping followed by spraying as disclosed on p. 17, lines 30-33 of the application.

For all the reasons above, claim 25, and claims 27 and 30-33 dependent thereon, are allowable. Removal of the rejection is respectfully requested.

Claims 25-33 have been rejected under 35 USC § 103(a) as obvious over Golomb. It is the position of the Examiner that the invention, "when taken as a whole", would have been *prima facie* obvious to one of ordinary skill in the art. This is not the case since Golomb fails to teach or suggest all the limitations of claim 25.

Nowhere does Golomb disclose, either expressly or inherently, adding polymeric particles containing a therapeutic substance to a coating material that includes a polymer and applying the coating material to a medical device to form a film layer of the polymer which includes the polymeric particles.

Golomb, rather, simply mentions the use of "...liquid carriers known in the art..." (Col. 6, lines 25-27) and only discloses generally "...coating of the delivery system on a balloon or a stent..." (Col. 6, lines 51-54). There is no mention of a polymeric material dissolved in a solvent present in the coating material in addition to therapeutic substance-containing polymeric particles nor is mention made of applying a fluid form of a coating material to a device and solidifying the coating material by allowing the solvent to evaporate, as required by claim 25.

Furthermore, the Examiner has provided no rationale for modifying the teachings of Golomb so that it teaches the above-mentioned claim limitations. The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. Indeed, the Supreme Court states that "Re-

jections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness". *KSR International Co. v. Teleflex Inc.* (KSR) (550 U.S. __, 82) (KSR). The Examiner, however, has failed to articulate why the teaching of Golomb could have been modified to teach the above claim limitations, rather simply states that the invention, "when taken as a whole", would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. The formulations of Golomb, however, are quite different from those of the present invention.

Golomb discloses agent-containing compositions that can be prepared as "...capsules, tablets, aerosols, solutions, suspensions or as a coating of a medical device such as a stent..." There is no teaching or suggestion that the coatings on such a medical device include capsules, tablets, aerosols, solutions or suspensions and an additional polymeric material, as required by claim 25 of the present invention. The present invention requires both therapeutic substance-containing polymer particles and a polymeric material dissolved in a solvent to be present in the coating material that is applied to the medical device.

Similarly, there would have been no reason for one skilled in the art to have looked to Golomb to teach the present invention since claim 25 requires two polymeric material components, i.e., a therapeutic substance-containing polymeric particle and a separate polymeric material dissolved in a solvent. Indeed, the present invention includes a polymeric material, i.e., polymeric particle, inside of another polymeric material, i.e., polymeric material dissolved in the solvent, whereas Golomb simply teaches a single polymeric material on a device. This would result in an end coating which includes drug containing polymeric particles encapsulated in a polymeric film layer. Thus, drug has to travel through not only the polymeric particle, but also the polymeric film layer to be released. The Examiner has not articulated why one skilled in the art would have looked to Golomb for guidance in teaching a 2-polymer delivery system, one encased in the other, for the delivery of drug.

Additionally, with respect to claim 30, nowhere does Golomb disclose, expressly or inherently, that the polymeric particles can be made by a water-in-oil emulsion

method, as presently claimed. Thus, claim 30 is independently patentable for this same reason as well.

Claim 31 is also independently patentable. As indicated above, a "hydrogel consistency" depends on the type and manner of processing but the Examiner has not shown how the teachings of Golomb would result in a hydrogel consistency.

Additionally, at least claim 33 is independently patentable. Nowhere does Golomb disclose, expressly or inherently, that the therapeutic substance can be a radioactive isotope. Thus, claim 33 is patentable and should be allowed.

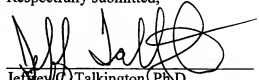
For all the above reasons, claim 25, and claims 26-33 dependent thereon, are allowable. Removal of the rejection is respectfully requested.

CONCLUSION

The undersigned authorizes the examiner to charge any fees that may be required or credit of any overpayment to be made to Deposit Account No. 07-1850.

Should the Examiner have any questions regarding this communication, the Examiner is invited to contact the undersigned at the telephone number shown below.

Respectfully submitted,



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